

### **REMARKS**

Of claims 1-58 which were contained in the pending application, claims 10-13 and 32 are now canceled. Claim 58 was canceled in the Preliminary Amendment.

#### **Rejections Under 35 U.S.C. §102(b)**

(¶3) The Examiner has rejected claims 1-15, 18-30, 32-42, 46, 47, and 49-57 under 35 U.S.C. §102(b) as being anticipated by Goldberg et al (WO 01/47368, pages 4-7, 9-15, 17, 19, and 42). In making this rejection, the Examiner states that Goldberg et al. discloses chewing gum including an amount of at least one biodegradable polymer as claimed by the Applicants (claims 10-12, 33-36, 49); having a molecular weight within the Applicants' claimed range, and a polydispersity within the Applicants' claimed range (claims 8 and 9). Further, the chewing gum of Goldberg et al. is free of non-biodegradable polymers, but includes conventional ingredients as claimed by the Applicant and in the amounts claimed by the Applicants (claims 14-30, 32, 37-39, 49). The chewing gum of Goldberg et al. is also coated with a coating as claimed by the Applicants. The Applicants respectfully traverse this rejection.

As an initial matter, in order for a §102 rejection to be valid, the art cited must teach all limitations required by the claims that define the present invention.

As currently amended, claim 1 requires a chewing gum comprising at least one biodegradable polymer, wherein the molecular weight of said biodegradable polymer is at least 105000 g/mol (Mn), and wherein the chewing gum is substantially free of non-biodegradable polymers.

A closer reading of Goldberg et al. disclose a combination of biodegradable and non-biodegradable polymers. Specifically, Goldberg discloses that

Apart from the degradable copolymers of the present invention, the composition of the gum base is not critical to the present invention. The composition of the gum bases of the present invention can vary .... [and] include both natural and synthetic elastomers and rubbers ... and synthetic elastomers such as butadiene-styrene copolymers, polyisobutylene, isobutylene-isoprene copolymers, polyethylene, mixtures thereof, and the like. (page 4, "Detailed Description of the Invention")

In contrast to Goldberg et al., the chewing gum of the present invention is "substantially free" of non-biodegradable polymers and also requires that the molecular weight of the biodegradable polymer is at least 105000 g/mol (Mn) (claim 1).

Since Goldberg et al. do not teach or suggest every element of the present invention as claimed, the Examiner's rejection under 35 U.S.C. §102(b) should be withdrawn.

#### **Rejections Under 35 U.S.C. §103(a)**

(¶4) The Examiner has rejected claims 16 and 17 under 35 U.S.C. §103(a) as being unpatentable over Goldberg et al. In making this rejection, the Examiner argues that finding the optimum amount of flavoring agent (claims 16 and 17) would require routine experimentation by one reasonably skilled in the art. The Applicants respectfully traverse this rejection.

Goldberg et al. teaches generally the state-of-the-art assumption that biodegradable polymers must be supplemented with non-biodegradable polymers in order to achieve as successful chewing gum. Goldberg et al. primarily focuses on the amounts and types of (biodegradable and non-biodegradable) monomers which may be used in practicing the technology. Goldberg et al. does not teach or suggest the

acceptable amounts of flavors (flavorants) which can be used in the chewing gum. In fact, Goldberg et al. only mentions the use of flavorants and does not give any range or amounts to one should use except for a single example with a defined precise amount of a flavor oil (see Example 49 in Goldberg et al.). There are no teachings or suggestions in Goldberg et al. which suggests an optimum amount of flavorant, especially in view of the fact that the single example shows the use of a flavorant at 1.800% (by weight). In addition, one skilled in the art would not look to Goldberg et al. for limits on flavor concentration ranges since Goldberg et al. uses a mixture of biodegradable & non-biodegradable polymers. This type of chewing gum has a different moisture content and hence very different properties from the chewing gum of the present invention, which is substantially free of non-biodegradable polymers. Accordingly, there is no teaching suggestion or motivation in Goldberg et al. that would lead one skilled in the art to utilize the concentration ranges of flavorants claimed in the present invention.

(¶ 5) The Examiner has rejected claim 31 under 35 U.S.C. §103(a), as being unpatentable over Goldberg et al. in view of Grijpma et al. (US 5,672,367, col. 3, line 4) or Li et al. (US 6,153,231, col. 7, lines 60-61). In making this rejection, the Examiner maintains that it would have been obvious to include a medicinal or pharmaceutical ingredient as an active ingredient in the gum of Goldberg et al., since such an ingredient is a conventional chewing gum component, as evidenced by either secondary reference. The Applicants respectfully traverse this rejection.

The addition of active ingredients to a gum can dramatically alter the textural properties of that gum, as these ingredients may be, for instance, acidic, basic, a salt, hydrophobic, hydrophilic, or hydrated. Hence, unless the gum bases are identical,

there is no way to predict whether or not a chewing gum with added active ingredients will have the desired textural properties for the consumer. Thus, one skilled in the art would understand that there is no teaching, suggestion or motivation in Goldberg et al. for the addition of other substances (besides flavorants) to the chewing gum. Goldberg et al. is directed to and discloses a chewing gum comprising both biodegradable and non-biodegradable polymers, the use of flavorants for such a gum, and how one skilled in the art may vary the monomers which comprise the chewing gum to achieve the desired textural properties of the gum.

One skilled in the reading Goldberg et al., in view of Grijpma et al. would not consider the use of actives in a chewing gum and specifically, the use of actives in a chewing gum that is substantially free from non-biodegradable polymers and where the chewing gum is required to have at least one biodegradable polymer that is at least 105,000 g/mol (Mn), as in claim 1 and dependent claim 31 of the pending application. Thus, there is no teaching suggestion or motivation in Goldberg et al. in view of Grijpma et al. that would lead one skilled in the art to include active ingredients in the present invention.

(¶ 6) The Examiner has rejected claims 43-45 and 48 under 35 U.S.C. §103(a), as being unpatentable over Goldberg et al. in view of Meyers (US 5,433,960, cols. 3 & 9-13 and claims 1, 16 and 27). In making this rejection, the Examiner argues that it would have been obvious to coat the chewing gum in Goldberg et al. with a coating as claimed by the Applicants in order to provide storage stability, as evidenced by Meyers. The Applicants respectfully traverse this rejection.

Goldberg et al. very generally describes a coated gum product (page 9, paragraphs 1 and 2). The gum material of Goldberg et al. is a combination of both

degradable and non-biodegradable polymers. The gum material of the present invention is substantially free of non-biodegradable polymers, and the polymers used are within a defined molecular weight range. It is well known to those skilled in the art that the characteristics of a chewing gum made from a mixture of biodegradable and non-biodegradable polymers is substantially different from the characteristics of a chewing gum that is made of biodegradable polymers and is substantially free on non-biodegradable polymers. Hence, the fact that the chewing gum of Goldberg et al. *might* be coated (note that there is only a general reference to coating a gum tablet in Goldberg et al. with no accompanying examples) would not lead one skilled in the art to coat a chewing gum that is made of biodegradable polymers and is substantially free on non-biodegradable polymers.

It is well known to those skilled in the art that the amount of water contained in a biodegradable chewing gum is critical - too much or too little moisture can have a detrimental impact on the consumer's perceived textural quality of the gum product. There is no teaching, suggestion or motivation in Goldberg et al., in view of Meyers, that would lead one skilled in the art to conclude that chewing gum that is made of biodegradable polymers which are substantially free from non-biodegradable polymers could be successfully coated.

Consequently, in view of the above arguments, the rejections under 35 U.S.C. §103(a), have been overcome and should be withdrawn.

#### **Double Patenting Rejection**

Claims 1-57 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims: 1-62 of co-pending application 10/472,122; claims 1-54 of co-pending application

10/472,154; claims 1-67 of co-pending application 10/528,926; claims 1-64 of co-pending application 10/529,133; claims 1-20, 22-26, and 28-42 of co-pending application 10/529,137; and claims 1, 2, 10, 11, 13-18, 24-26 and 28-54 of co-pending application 11/088,109.

Upon indication of allowable subject matter in this case, Applicants will file the appropriate terminal disclaimers in order to overcome these rejections.

The present application as amended herein, is now in form for allowance and early reconsideration and allowance of the claims, as currently pending, is earnestly solicited.

Respectfully submitted,

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